This document was submitted to EPA by a registrant in connection with EPA's evaluation of this chemical, and it is presented here exactly as submitted.

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May 12, 2000

Via E-Mail and Hand Delivery

Ms. Kimberly Lowe
Office of Pesticide Programs
Special Review and Reregistration Division
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania, Avenue, N.W.
Washington, DC 20460

Re: Revised Preliminary Risk Assessment for Dichlorvos

Dear Ms. Lowe:

On behalf of Amvac Chemical Company, we submit with this letter a list of some of the many key errors and omissions in EPA's "Revised Preliminary Risk Assessment for Dichlorvos" (PRA) dated April 5, 2000. We wish to highlight in this letter our grave concerns with the PRA and the process by which it is being issued.

This PRA is substantially different from the prior draft, and appears to have been prepared in great haste. Rather than carefully and completely evaluating the database, EPA has rushed to issue an assessment to meet a self-imposed goal of completing the organophosphate risk assessments by a time certain. As a result, the present version of the PRA contains substantially more errors than the prior draft of the document and does not incorporate many of Amvac's

comments on the prior draft.[1/] Moreover, the PRA is based on policies and guidelines that have the force and effects of rules but that have not been subject to legally required administrative procedures.

For these reasons, the PRA is not fit for release to the public as EPA's statement of its position on dichlorvos (DDVP). Release of the PRA without correcting the many fundamental errors it contains would be an arbitrary and capricious action and would disregard Amvac's due process rights, as well as fundamental fairness. EPA thus must withdraw this PRA and revise it substantially before releasing it publicly.

DISCUSSION

Given the substantial changes from the prior version of the PRA, and the limited review time, Amvac has not had an adequate opportunity to conduct the comprehensive review necessary to identify all of the errors and flaws in the document.[2/] In the short time that Amvac has

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1/ Amvac incorporates by this reference all of its comments stated in its February 11, 1999, submission addressing the prior version of the PRA that are not addressed in the current version of the PRA. Amvac also incorporates by this reference the legal concerns stated in the February 11, 1999, submission. These concerns are equally applicable to the current version of the PRA. Amvac additionally incorporates by this reference its letter dated March 17, 2000, addressing the pig data, which Amvac believes are critical to an accurate risk assessment.

2/ This fact is violative of Amvac's due process rights, for many of the same reasons outlined in Amvac's February 11, 1999, submission. In brief, Amvac has not had adequate time to review and comment on the PRA. It is a clear violation of due process to present an alleged finding as an agency decision where an inadequate opportunity to comment was provided. *See, e.g., Grossman v. Axelrod*, 466 F. Supp. 770, 775 (S.D.N.Y. 1979), *aff'd* 646 F.2d 768 (2d Cir. 1981); *Synthetic Organic Chem. Mfrs. Ass'n v. Brennan*, 506 F.2d 385, 388-89 (3d Cir. 1974), *cert. denied sub nom., Oil, Chem. & Atomic Workers Int'l Union*, 423 U.S. 830 (1975) (Court remanded standards to the Department of Labor where the agency did not give interested parties adequate time to comment because it published a proposed rule before the advisory committee submitted its final report on the rule). *See also Chemical Waste Management, Inc. v. E.P.A.*, 976 F.2d 2, 28 (D.C. Cir. 1992), *cert. denied sub nom., Chemical Mfrs. Ass'n v. EPA*, 507 U.S. 1057 (1993); *Florida Power & Light Co. v. United States*, 846 F.2d 765, 771 (D.C. Cir. 1988), *cert. denied,* 490 U.S. 1045 (1989) (agency must "provide sufficient factual detail and rationale for the rule to permit interested parties to

had to review this document, however, the Company's scientific experts have identified over 60 critical errors and omissions. Amvac's specific comments are attached hereto. Among the errors and omissions that Amvac has identified are the following:

- The human data have been dismissed out-of-hand until the development of a new EPA policy on the use of human data. DDVP cannot be fully evaluated without a full and complete consideration of the extensive body of human data. To ignore it is arbitrary and scientifically indefensible.

- EPA has arbitrarily raised developmental toxicity concerns without basis using a very poorly conducted guinea pig developmental toxicity study conducted by Mehl, while ignoring the extensive literature on the developmental effects of DDVP and trichlorfon in the pig. This is scientifically indefensible and arbitrary.

- EPA is arbitrary and scientifically unsound in dismissing a large body of studies with the contention that these studies do not demonstrate dose response or are not useful to quantify risk. To the contrary, many of these studies do contain quantitative information and are highly relevant to a risk assessment of DDVP.

- EPA is also arbitrary and incorrect in claiming that new information provided by Amvac does not add any new information to the animal database.

- EPA is incorrect that the Leary, *et al.* study does not present enough detail "as a journal article" to allow a complete assessment of the study. In fact, the Arizona III study, a part of the Leary, *et al.* study which contains detailed quantitative data, was supplied to EPA as a separate report on May 4, 1999.

- EPA changed the toxicity value for short-term exposure from a human acute study to a short-term animal study. Due to this change, the exposure metrics

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comment meaningfully."); *Horsehead Resource Dev. v. Browner*, 16 F.3d 1246, 1267-68 (D.C. Cir.), *cert. denied sub nom., Cement Kiln Recycling Coalition v. Browner*, 513 U.S. 816 (1994). While these cases address the requirement for notice and comment in the context of rulemaking, the principles are equally applicable to the issuance of a risk assessment -- such as the PRA -- which has the *de facto* effect of a final agency action.

for DDVP uses are not reflective of the toxicity metrics, making the assessments based upon them scientifically indefensible and arbitrary. For example, the period for household spray exposure is very brief. Yet, a short-term risk scenario is evaluated for this situation. There is no basis in fact for assuming that someone sprays inside the home every day for 7 consecutive days. The PRA erroneously and indefensibly, however, bases the toxicity value on a 7-day or greater exposure time period. The uses of DDVP -- which in almost all cases result in acute exposures -- require an acute toxicity study to be used for scientifically defensible risk estimates. The PRA does not do this and thus is scientifically indefensible. Issuing it without correcting this flaw would be arbitrary and capricious.

- EPA relied on a rabbit developmental study for the short-term risk scenario. The toxicological endpoints used are a decrease in body weight and clinical observations indicative of cholinergic signs at 2.5 mg/kg/day. Neither effect occurs in the study, however. The NOAEL listed by EPA is 0.1 mg/kg/day for several days of exposure. This is not in agreement with the study report. The report is clear that neither body weight nor clinical observations were affected in the 2.5 mg/kg/day dosage group.

  -- **Body weights**
  The Abstract of the Report of the study states on page 7: "Maternal body weights and weight gains were statistically equivalent at all time points and intervals examined." This is supported by the data in the report in Table 2, page 20.

  -- **Clinical Observations**
  The Abstract of the Report of the study states on page 8: "Maternal clinical signs of toxicity were limited to doses at 7.0 mg/kg/day." This is supported by the data in the report in Table 3, on page 23.

- The NOAEL in the rat acute neurotoxicity study should not be treated as a LOAEL, and there is no reason to add an additional 3X factor. Further, it is unfair, scientifically unsound, and arbitrary not to use the human study to set the NOAEL.

- EPA has not corrected the gross errors in its calculations based on the Blair *et al.* study, as discussed in Amvac's February 11, 1999, comments on the prior version of the PRA.[3/]

- The Revised PRA also fails to correct the fundamental misrepresentation of critical data from the Blair *et al.* study as discussed in Amvac's February 11, 1999, comments on the prior version of the PRA.[4/]

Based on these flaws and the additional errors listed in the attachment to this letter, Amvac urges EPA to take the time to correct and properly complete this PRA, rather than rushing to judgment under an arbitrary deadline, and sacrificing good science in the process. EPA should give consideration to the complete database in a manner consistent with its policies and sound science. The present draft does not come close to meeting this standard. Publishing the PRA in its current inaccurate and incomplete form is scientifically indefensible, and would be arbitrary, capricious, and contrary to the procedural and substantive standards established under the Administrative Procedure Act (APA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and EPA guidelines.

EPA Has Failed To Consider All Relevant Information As Required By Law

The PRA does not consider, or even mention, many significant animal studies, and arbitrarily relies on certain studies to the exclusion of other highly relevant data. In addition, EPA has failed to consider adequately human toxicity data, as well as highly relevant data on exposure, inter-individual variability, and sensitive subpopulations. A full and complete consideration of all available data is critical to a scientifically sound risk assessment.

In particular, EPA has relied on a very poorly conducted and poorly reported study by Mehl *et al.* to determine the potential developmental toxicity of DDVP, and ignored numerous published studies of the developmental effects of DDVP and trichlorfon in pigs. This reflects an arbitrary selection of data to support EPA's position. EPA also has failed to consider other animal data pertaining to the cholinesterase effects of DDVP.

3/ These significant errors are discussed on pages 8-9 of Amvac's February 11, 1999, submission.

4/ These critical errors are discussed on pages 7-8 of Amvac's February 11, 1999, submission.

EPA additionally has declined to consider the large body of human data, despite the wealth of information provided by this database. The human database includes studies that were designed specifically to look for early signs of cholinesterase inhibition, such as pupillary reactivity and visual acuity. Most of the studies include the documentation of subjective symptoms, as well as clinical assessments of any abnormal changes, including measurements of cholinesterase in red blood cells (RBCs) and plasma. Certain studies made other physiological measurements to assess cardiac, neurological, lung, and kidney function. Taken as a whole, the human studies show that humans are not more sensitive than animals to the effects of DDVP.[5/]

Human data also show that there is little inter-individual variability from exposure to DDVP. The majority of the data on exposed sensitive subpopulations show little to no effects from exposure to DDVP. Children exposed to DDVP in hospital pediatric wards in Italy showed no unfavorable effects.[6/] Similar results were seen in diseased adults and in very sick adults.[7/] The PRA ignores these important data.

The law is clear that an agency must consider all relevant information in its decision-making process -- in this case, a large body of existing animal, human, and exposure data that the PRA fails to address -- and must conduct its decision-making "in a principled fashion."[8/] An agency

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5/ These data are discussed in Amvac's earlier submissions to EPA.

6/ Cavagna, G., Locati, G., and Vigliani, E.C. (1970). "Exposure of Newborn Babies to Vapona Insecticide." *European J. of Toxicol.* III:49-57 (MRID Number 00056187).

7/ Cavagna, G., Locati, G., and Vigliani, E.C. (1969). "Clinical Effects of Exposure to DDVP (Vapona) Insecticide in Hospital Wards." *Arch. Environ. Health* 19:112-123 (MRID Number 00060476); Chavarria, A. Pena, Swartzwelder, J.C., Villarejos, V.M., Kotcher, E., and Arguedas, J. (1969). "Dichlorvos, an Effective Broad – Spectrum Anthelmintic." *Am. J. of Tropical Medicine and Hygiene* 18(6):907-911.

8/ *See Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402 (1971); *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983); *NCAMP v. Thomas*, 815 F.2d 1579, 1582 (D.C. Cir. 1987); *NCAMP v. Thomas*, 809 F.2d 875, 882 (D.C. Cir. 1987) (court found that EPA had "acted arbitrarily and capriciously by failing to give appropriate consideration to relevant factors and reversing its position on the health risks of EDB" and remanded the matter to EPA with instructions to address the issue by giving proper consideration to the statutory factors).

decision is arbitrary and capricious if the agency has ignored information in its possession or reached a decision that runs counter to the evidence before the agency.[9/]

Agency actions that fail to address fundamental issues raised by parties entitled to protection have also been found to violate "basic concepts of fair play."[10/] EPA cannot make a reasoned, "principled" decision on the risk of use of Amvac's products without fully considering all data in its possession. Indeed, in a situation analogous to the DDVP fact situation, the United States Court of Appeals for the Fifth Circuit found that the Consumer Product Safety Commission's (CPSC) exclusive reliance on a rat study inadequate to support its rule where the CPSC failed to consider a body of available epidemiology studies.[11/]

9/ *See Retail Store Employees Union, Local 880, R.C.I.A. v. FCC*, 436 F.2d 248, 254 (D.C. Cir. 1970) (citations omitted). *See also Sierra Club v. Interstate Commerce Comm'n*, 1978 Fed. Carr. Cas. (CCH) ¶ 82,768 (D.C. Cir. 1978).

10/ *Wellford v. Ruckelshaus*, 439 F.2d 598, 602 (D.C. Cir. 1971) ("We are troubled by the possibility that the Secretary failed to give petitioner's allegations [made in a petition to suspend use of a pesticide] the careful consideration to which they were entitled . . ."); *EDF v. Hardin*, 428 F.2d 1093, 1100 (D.C. Cir. 1970) (court directed EPA to provide detailed explanation for failure to take action to suspend DDT in face of "impressive evidence presented by petitioners."); *Public Citizen Health Research Group v. Tyson*, 796 F.2d 1479, 1497, 1507 (D.C. Cir. 1986) (court remanded case to the Occupational Safety and Health Administration (OSHA) for failure to set short-term exposure limits (STEL) on grounds that OSHA's deliberations on this issue were incomplete and OSHA had "entirely failed to consider an important aspect of the problem . . ."). *See also Olenhouse v. Commodity Credit Corp.*, 42 F.3d 1560, 1583 (10th Cir. 1994), *citing Garvey v. Freeman*, 397 F.2d 600, 612 (10th Cir. 1968); *Gulf S. Insulation v. CPSC*, 701 F. 2d 1137, 1146 (5th Cir. 1983) (Consumer Product Safety Commission's exclusive reliance on a rat study was inadequate to support its rule where the Commission failed to consider a body of available epidemiology studies); *Love v. Thomas*, 858 F.2d 1347, 1358-1363 (9th Cir. 1988) (the court found that EPA's decision to suspend the use of the pesticide dinoseb was arbitrary and capricious, an abuse of discretion, and not in accordance with FIFRA because EPA failed to evaluate information in its possession about potentially disastrous and unique impacts of the suspension on agriculture in the Pacific Northwest), *cert. denied sub nom. AFL-CIO v. Love*, 490 U.S. 1035 (1989).

11/ *Gulf S. Insulation v. CPSC*, 701 F. 2d at 1146.

In sum, EPA's public release of the PRA, which fails to consider a significant body of relevant information, would be arbitrary and capricious, and would violate basic concepts of fair play and principled, sound decision-making.

EPA Has Acted Contrary To Its Own Policies

In ignoring a large body of data, EPA has acted in a manner contrary to its own regulations, policy, and precedent. First, EPA has failed to follow a weight-of-the-evidence approach. EPA's risk assessment guidelines demand that it evaluate the "total weight of the evidence," a concept which includes all available, reliable data and information, not arbitrarily selected data. This weight-of-the-evidence approach is consistent throughout EPA's risk assessment guidelines.

For example, in its Guidelines for the Health Assessment of Suspect Developmental Toxicants, EPA states:

> [T]he guidelines emphasize that risk assessments will be conducted on a case-by-case basis, giving full consideration to all relevant scientific information. This case-by-case approach means that Agency experts review the scientific information on each agent and use the most scientifically appropriate interpretation to assess risk. The guidelines also stress that this information will be fully presented in Agency risk assessment documents, and that Agency scientists will identify the strengths and weaknesses of each assessment by describing uncertainties, assumptions, and limitations, as well as the scientific basis and rationale for each assessment.[12/]

Further, EPA's present policy on the use of data on cholinesterase inhibition for risk assessments explicitly requires a consideration of all animal and human data, giving precedence to available human data. EPA states:

> A weight of the evidence approach for evaluation of any ChE inhibitor should consider all of the available data from animal and human studies, and human exposures to identify the hazards and the exposure levels at which they occur. First the individual studies are

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12/ 51 Fed. Reg. 34028 (Sept. 24, 1986).

> evaluated, then all studies and their relation to one another are examined in concert.
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> Typically, a critical effect level is selected for a route and duration of exposure that represents the most sensitive effect seen. Based on considerations of the weight of the evidence from all of the studies as a group, this level may or may not be the lowest one in which an effect was seen. *Valid and reliable human data, when available, take precedence.*[13/]

EPA emphasized that the risk characterization must be based on a broad evaluation of the pattern of observed toxicity, including such factors as the "relationship between exposures and different effects," "the nature and severity of effects seen; the slope of the dose effect curves for different effects, and the completeness of the effects evaluated."[14/] Other factors that EPA identified as "important to consider in the total data base" include "the number of human incidents reported, and the scope of the effects evaluated."[15/] Finally, EPA stated that "the strengths and weaknesses in the data base should be summarized and the uncertainties in defining the critical effects should be clearly documented."[16/] No such considerations are included in EPA's PRA.

EPA has not articulated any sound basis here for radically departing from its well-established weight-of-the-evidence approach and ignoring much of the available database, contrary to its policy and well-established principles of science. It is a fundamental principle of administrative law that an agency must follow its own precedents, absent a rational explanation for

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13/ Office of Pesticide Programs, Science Policy on the Use of Data on Cholinesterase Inhibition for Risk Assessments of Organophosphate and Carbamate Pesticides (Oct. 27, 1998) at 14 (Science Policy Document), <http://www.epa.gov/oppfead1/trac/science/index.htm> (PDF format).

14/ *Id.* at 16.

15/ *Id.*

16/ *Id.*

departure from such precedent.[17/] EPA's attempt here to ignore a highly relevant body of data is clearly contrary to EPA policies and the requirements of law and good science.

EPA Cannot Reject Its Human Testing Policy Or Change Other Critical Policy Without Notice And Comment Rulemaking

EPA's weight-of-evidence approach, requiring the use of all available data, and particularly, human data, is formally set forth as EPA policy in numerous agency guidelines issued with notice and comment procedures. Indeed, EPA's current cholinesterase risk assessment policy mandates the use of any available valid and reliable human data over animal data. In the prior version of the dichlorvos PRA, EPA did in fact rely on certain human studies -- studies performed by Amvac with the concurrence of EPA. These studies were reviewed by EPA, and found to be scientifically acceptable. The revised dichlorvos PRA places no reliance on these important data, however, nor on the extensive human data base conducted under a broad range of use conditions, and covering the entire spectrum of human subjects in age, sex, and health condition. EPA justifies

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17/ *See Vitarelli v. Seaton*, 359 U.S. 535, 539-40 (1959); *United States v. Caceres*, 440 U.S. 741, 758-759 (1979) ("government officials no less than private citizens are bound by rules of law. Where individual interests are implicated, the Due Process Clause requires that an executive agency adhere to the standards by which it professes its action to be judged."). *National Conservative Political Action Comm. v. FEC,* 626 F.2d 953, 959 (D.C. Cir. 1980) ("Agencies are under an obligation to follow their own regulations, procedures, and precedents, or provide a rational explanation for their departures."); *Northwest Airlines, Inc. v. U.S. Dep't of Transp.*, 15 F.3d 1112, 1121 (D.C. Cir. 1994) ("An Agency should not gloss over or swerve away from prior precedent without discussion."); *Greater Boston Televison Corp. v. FCC*, 444 F.2d 841, 852 (D.C. Cir. 1970), *cert. denied*, 403 U.S. 923 (1971) ("[A]n agency changing its course must supply a reasoned analysis indicating that prior policies and standards are being deliberately changed, not causally ignored, and if an agency glosses over or swerves from prior precedents without discussion it may cross the line from the tolerably terse to the intolerable mute.")(citation omitted). *See also Service v. Dulles*, 354 U.S. 363, 388 (1957); *Morton v. Ruiz*, 415 U.S. 199, 235 (1974); *Lucas v. Hodges*, 730 F.2d 1493, 1504 n.20 (D.C. Cir. 1984) ("it is a familiar principle of federal administrative law that agencies may be bound by their own substantive and procedural rules and policies, whether or not published in the Federal Register, if they are intended as mandatory"), *vacated as moot*, 738 F.2d 1392 (D.C. Cir. 1984); *Western States Petroleum Ass'n v. EPA*, 87 F.3d 280, 284 (9th Cir. 1996) ("EPA 'may not depart, sub silento, from its usual rules of decision to reach a different, unexplained result in a single case.'")(citation omitted).

this approach on the grounds that it does not want to make any final regulatory decisions based on a human study until EPA has developed a new human testing policy. Rather than use its existing long-standing, scientifically valid policy of giving precedence to human data, EPA has stated that it will rely only on animal data.

Thus, without changing its policy -- in fact, even before the development of a new human testing policy -- EPA has turned its back on the use of any human data in the risk assessment process for dichlorvos. This is not only bad science and poor judgment, but also runs counter to the basic due process requirement for administrative agencies to use the notice and comment process in issuing guidance that mandates the approach the agency will follow. The recent D.C. Court of Appeals decision in *Appalachian Power Company v. EPA*[18/] makes very clear that EPA cannot bypass notice and comment requirements in changing agency guidance policy, where the agency, as a practical matter, relies on the policy as binding or the policy reflects a settled position which has legal consequences. In the words of the Court:

> But we have also recognized that an agency's other pronouncements can, as a practical matter, have a binding effect .... If an agency acts as if a document issued at headquarters is controlling in the field, if it treats the document in the same manner as it treats a legislative rule, if it bases enforcement actions on the policies or interpretations formulated in the document, if it leads private parties or State permitting authorities to believe that it will declare permits invalid unless they comply with the terms of the document, then the agency's document is for all practical purposes "binding."[19/]

EPA's rejection of its long-standing and well-established policy on the use of human data has undeniable legal consequences for the dichlorvos risk assessment. Rather than rely on the totality of the evidence, EPA has confined its purview to an arbitrarily limited subset of the data and reached different regulatory conclusions than would otherwise be the case. EPA cannot implement such a drastic policy change without notice and comment. EPA's actions here, in fact, point out the value and need for notice and comment -- to allow the scientific community, regulated industry, and the public the opportunity to dissuade the agency from developing a new policy that is out of touch with basic scientific principles, good decision-making, and common sense.

18/ *Appalachian Power Co. v. EPA*, No. 98-1512 (D.C. Cir. Apr. 14, 2000).

19/ *Id.*

In *Appalachian Power Company*, the court recognized some of those very types of concerns in rendering its conclusion, warning with disapproval:

> Law [in the case at hand] is made, without notice and comment, without public participation, and without publication in the Federal Register or the Code of Federal Regulations. With the advent of the Internet, the agency does not need these official publications to ensure widespread circulation; it can inform those affected simply by posting its new guidance or memoranda or policy statement on its web site. An agency operating in this way gains a large advantage. "It can issue or amend its real rules, *i.e.*, its interpretative rules and policy statements, quickly and inexpensively without following any statutorily prescribed procedures." Richard J. Pierce, Jr., Seven Ways to Deossify Agency Rulemaking, 47 Admin. L. Rev. 59, 85 (1995).9.[20/]

In *Appalachian Power* the court clearly found this type of EPA action impermissible. EPA should heed the court's decision here.

Release of the PRA Would Result in Costly and Unfounded Product Deselection

It is fundamentally unfair and damaging to the public, as well as Amvac, for EPA to issue an erroneous risk assessment. Significant business losses can occur as a result of EPA's arbitrary release of a scientifically indefensible document that will nevertheless cause fear and concern -- albeit unwarranted -- among consumers who rely on EPA review and conclusions. This fear and concern -- even though based on scientifically indefensible conclusions -- will cause product deselection, *i.e.*, customers' choice of alternative products. Releasing a scientifically indefensible document in these circumstances is arbitrary and capricious and will cause unnecessary and unfounded losses to sellers of DDVP. A suggestion by EPA that a product poses any type of problem has far-reaching consequences for public acceptance of the product not only within the U.S., but also abroad. Further, when EPA issues a document that needs to be radically revised to be consistent with the scientific data, the public loses confidence in the ability of EPA to do its job properly.

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[20/] *Id.*

For all these reasons, Amvac strongly urges EPA not to issue publicly this erroneous and incomplete document as EPA's current statement of its assessment of DDVP. Amvac urges EPA instead to revise the PRA as discussed in this letter and the attachment to it.

Sincerely,

Lynn L. Bergeson
Lisa M. Campbell
Cara Jablon

Attachment
cc: Mr. Robert C. McNally (via e-mail)
Mr. Jack E. Housenger (via e-mail)
Marcia E. Mulkey, Esquire (via e-mail)

AMVAC

Amvac Chemical Corporation's Errors and Corrections to *Revised Preliminary HED Risk Assessment for Dichlorvos* dated April 5, 2000

Page	Comment
3	***Mehl et al., 1994.*** The PRA states that this very poorly conducted and very poorly reported study by Mehl *et al.*, 1994 raises concerns regarding the potential of dichlorvos to affect the developing offspring. Numerous published studies of the effects of dichlorvos on developmental effects in pigs have not been mentioned and appear not to have been reviewed, however. This is a significant error in the PRA, which weakens the PRA's reliability. If not corrected, this error would make the issuance of the PRA arbitrary and capricious. (Amvac previously submitted a list of references to EPA in a letter from Ian S. Chart to Robert C. McNally dated March 17, 2000.)
3	***Trichlorfon.*** The PRA mentions the trichlorfon studies in the open literature. The PRA does not address, however, the trichlorfon pig studies in the literature and the contrasting results between the effects on piglets treated with trichlorfon and those treated with dichlorvos. If not corrected, this error would make the issuance of the PRA arbitrary and capricious. EPA has used an arbitrary pattern of reviewing studies, selecting isolated references supporting its assessment and not mentioning or addressing those that demonstrate a completely different developmental toxicology profile of the two pesticides.
3	***FQPA Factor.*** The PRA provides a rationale for reducing the FQPA factor from 10, but provides no rationale for why the factor is 3, and not 1. This error is linked to EPA's failure to review the extensive literature on the developmental effects of dichlorvos and trichlorfon in the pig literature mentioned above.
3	***Uncertainty Factors.*** The PRA states that the uncertainty factors ranged from 10 to 300. This is not in agreement with the listing of uncertainty factors on page 16.
5	***Chronic Dietary (Food).*** Two different systems were used for dietary analysis -- DRES and DEEM. It would be more appropriate to use the same system for both acute and chronic.
6	***Resin Strips.*** The target MOE is 300, which does not agree with the stated target MOE of 90 on page 16. The target MOEs on page 6 of 300 and page 16 of 90 also do not agree with the target MOE of 100 stated on page 47.

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6 ***Resin Strips.*** Amvac presented information to EPA on other sizes of resin strips at a meeting on February 10, 2000. This information should be incorporated into the assessment.

6 ***Pet Flea Collars.*** EPA should use the results of the EPA-funded research nearing completion on potential exposure to flea collars for evaluation of DDVP pet flea collars. Additionally, it is not appropriate to use a study submitted by a previous registrant if the current registrant cannot review the study (*see* EPA Memorandum from David Jaquith to Christina Scheltema, regarding "Response to Comments from EXPOSAC on Exposure Assessment for Dichlorvos (DDVP) from Flea Collars" at 5 (data from the original study not available).

6 ***Pet Flea Collars.*** The target MOE of 100 does not agree with the target MOE of 300 on page 48 or the target MOE of 300 for resin strips (the section preceding this section in the PRA).

7 ***Warehouse Treatment and Re-entry.*** EPA assumed a 6-hour re-entry interval (REI). The label, however, requires a 24-hour REI, except when monitoring is conducted.

11 ***Carcinogenicity.*** For the chronic carcinogenicity study entry, the Results are listed as "Evidence of carcinogenicity." In fact, EPA and SAP have concluded that the evidence is only suggestive. The word "suggestive" should be added to the Results.

11, 16 ***Developmental Toxicity Rabbit.*** The NOAEL for maternal toxicity is listed as 2.5 and for developmental toxicity at $\geq$ 7 mg/kg/day. The oral NOAEL from this study on page 16 is listed as 0.1 mg/kg/day, which conflicts with the information on page 11.

12 ***Literature Studies. Mehl et al., 1994.*** Information from the authors and laboratory regarding this study should be verified and added. A submission regarding this study was made to EPA on January 19, 1999. A copy of the study was submitted by Amvac to EPA on March 21, 2000.

12, 13 ***Discussion of Studies Submitted by Amvac to EPA.*** While the interpretation of the studies may be a subject for ongoing debate with EPA, several errors are made in the statement. These include the following:

a. There are in excess of 100 studies that have been submitted.

b. The age of the studies is stated as 30 years old and is reported in a manner indicating that old studies are inherently poor and new ones are inherently good. The Mehl *et al.*, 1994 study is extremely poorly conducted and misrepresented. The fact that the study was reported in 1994 does not make it "good." Relying solely on the age of a study to determine its worth is arbitrary and capricious, and shows bias not scientifically supported by the actual data.

c. The PRA comments that many studies do not demonstrate dose response or are not useful to quantify risk. This is incorrect. Many do contain quantitative information. Dose response is not needed to make a study very useful for determining the relative sensitivity of man and animals. The studies adequately support that man and animals are equisensitive to the cholinesterase-inhibiting properties of dichlorvos. While one study in isolation may not be sufficiently robust, 30 studies taken together are quite compelling.

13 ***Literature Animal Studies***. The PRA states that the new information does not add any new information to the relevant database for animal studies. This is not true. Several examples of studies (noted below) that were conducted to determine developmental sensitivity of animal mothers compared to offspring and fetuses are not mentioned or reviewed by EPA in any documents Amvac has seen. It is scientifically indefensible, arbitrary, and capricious to rely on two guinea pigs in the Mehl study given subcutaneous injections of dichlorvos at near lethal levels knowing the animals were not treated at the same time as each other or the control animals and to dismiss completely well-conducted, controlled, and reported studies on the very same developmental endpoint. Studies that the PRA does not mention and that are directly relevant to this point include the following:

a. Tracy, R.L., *et al.* (1960). A study of the comparative sensitivity of dichlorvos to the suckling newborns of rats and cows exposed to toxic doses of dichlorvos daily, demonstrating that the mothers are more susceptible to the cholinergic effects than are the offspring.

b. Stanton, *et. al.* (1979). In this study, pregnant sows were treated with DDVP. Doses that caused cholinesterase activities in blood and plasma to be 30 percent or less of pretreatment levels in the pregnant sows did not result in any change in cholinesterase in the fetuses. This study shows that DDVP does not cross the placental barrier.

c. Wrathall, *et. al.* (1980). DDVP was without any effect on offspring of the pig when administered to pregnant sows daily for a 30-day period from day 41 to day 70. Administration includes the period when trichlorfon exerts its teratogenic effects, as thichlorfon has been shown to be teratogenic in the pig when administered only on day 55. This study was specifically designed to look for the types of lesions that trichlorfon produces in the brain and cerebellum of the pig and guinea pig. None were apparent. It also was concluded at adequate high doses of DDVP, as the cholinesterase levels of whole blood were depressed to approximately 30 percent of pretreatment levels.

d. Potter, *et al.* (1973). There is no evidence that DDVP or any DDVP metabolites are present in the offspring of treated sows.

13 ***Arizona III Study.*** The PRA states with regard to the Leary, *et al.* study that "as a journal article it was not presented in enough detail for complete assessment of the information to be made, although it provides valuable information." (The quoted conclusion for this argument is from a 1993 assessment of DDVP.) In fact, the Arizona III study, the most important part of the Leary *et al.* study, was supplied to EPA as a separate report on May 4, 1999. The Arizona III study contains all of the detailed information and individual data from the most important and useful part of the Leary study. Taken together, all of the data exist for this study to be used for regulatory purposes.

14 ***FQPA Safety Factor.*** The Tarplee 2000 reference is not on the reference list.

14 ***Cancer Classification.*** Item #1 should indicate that corn oil was the vehicle and that corn oil can suppress the spontaneous control values for MCL. The dichlorvos-treated animals have MCL rates like normal control animals not given corn oil. Further, there is no increase in MCL with increasing dose. This is the key issue for DDVP noted by both SAP and EPA reviews.

16 ***Table 3.*** There are inconsistencies throughout the table. Sometimes LOAELs are listed when they are not used in the RfD calculations. In some cases RfDs are indicated, whereas in others they are not. It is not clear what the RfD is in these cases. Additionally, it is unclear if the NOAELs or LOAELs are used to calculate the RfDs in some cases.

16 ***Table 3.*** The Acute Dietary (animal) endpoint listed is the LOAEL of 35 mg/kg. In fact, the NOAEL is 0.5, and that is used in the RfD calculation to arrive at 0.0017 mg/kg/day.

16 ***Table 3***. The chronic inhalation uncertainty factor is listed as 30 in Table 3. Footnote c states this factor includes 10X for intraspecies variation and 3X for use of a LOAEL. Table 3 does not state the LOAEL for chronic inhalation, nor is one used.

16 ***Table 3.*** The column heading **DOSE (mg/kg/day) UF/MOE** does not describe the information listed under that column. The information under that column heading is inconsistent for each exposure scenario.

16 ***Table 3.*** The column heading **ENDPOINT** is inconsistent. It sometimes lists effects, sometimes RfDs. For some scenarios, RfDs are not shown anywhere in the document.

16 ***Acute Dietary***. The acute Neurotoxicity Study in Rats carefully monitored animals for clinical observations indicative of organophosphates. The NOAEL therefore should not be treated as a LOAEL and the additional 3X factor should not be added. It is scientifically indefensible, arbitrary, and capricious not to use the human study to set the NOAEL, not to use the human study to reduce the interspecies uncertainty factor, and then to add another 3X factor to the NOAEL in a carefully monitored study. Acute studies typically measure clinical observations as the toxicological endpoint. There is no evidence to support using subtle cholinesterase changes as an index of acute toxicity.

16 ***Cancer Oral Route.*** The term N/A in the table is not defined in the footnotes.

16 ***Short-Term Inhaltion and Dermal (Animal).*** The NOAEL listed is 0.1 mg/kg/day based on cholinergic signs and decreases in body weight at 2.5 mg/kg/day. This is not in agreement with the study report. The report is clear that neither body weight nor clinical observations were affected in the 2.5 mg/kg/day dosage group.

Body weights
The Abstract of the Report of the study states on page 7: "Maternal body weights and weight gains were statistically equivalent at all time

points and intervals examined." This is supported by the data in the report in Table 2 on page 20.

Clinical Observations
The Abstract of the Report of the study states on page 8: "Maternal clinical signs of toxicity were limited to does at 7.0 mg/kg/day." This is supported by the data in the report in Table 3 on page 23.

17 ***Short-Term Dermal (and Inhalation) Developmental Toxicity Rabbit.*** The NOAEL for maternal toxicity is listed as 2.5 mg/kg/day on page 11. This is in disagreement with the discussion on page 17, which states that body weights and clinical observations were affected in the 2.5 mg/kg/day dosage group. Neither body weights nor clinical observations were affected at 2.5 mg/kg/day. Thus, the statement on page 17 is in error and is not supported by a review of the study data.

While two animals died at 2.5 mg/kg/day, they died on days 12 and 15 (treatment days 6 and 9). Clinical observations of cholinesterase inhibition were not noted in either case. This is not an indication of short-term toxicity as expected from an organophosphate.

This study is a poor one to use for the determination of short-term toxicity as defined by EPA for many reasons, including the following:

a. The study was not designed nor intended to measure short-term toxicity.

b. Neither body weights nor clinical observations were affected by treatment, even in the mid-dosage group.

c. For an organophosphate, clinical observations would be the most likely adverse affect of treatment observed in this study. Clinical observations attributed to treatment were noted only at the highest dose of 7.0 mg/kg/day.

d. Rabbits vary substantially and often have respiratory infections, which make their overall health condition not stable. Animals with respiratory infections often die, and sporatic deaths can be more likely when challenged with a chemical. For these reasons, rabbits are not good indicators of toxicity and are generally considered not to be useful for measurement of repeat dose toxicity.

e. Adequate human data exist to determine a NOAEL for cholinesterase inhibition from a few days of exposure to dichlorvos.

18 ***Chronic Inhalation.*** The target MOE is given as 100 (or as 30 in the previous sentence). This is in disagreement with the MOE given on pages 6 and 47.

25 ***Chronic Dietary Assessment.*** The data in the DRES system used for the chronic dietary assessment is from USDA food consumption surveys from 1977-1978. It would be more appropriate to use the DEEM system which incorporates consumption data from 1989-1992 for the chronic assessment. Additionally, this would allow similar data to be used for both the acute and chronic dietary assessments.

41 ***Drinking Water Risk Estimates.*** The PRA states a potential risk concern for surface water based on a Tier I model for estimating surface water concentrations. In OPP's November 17, 1997, Memorandum from Stephen Johnson to OPP Division Directors, regarding "Interim Approach for Addressing Drinking Water Exposure," EPA stated:

> OPP wishes to emphasize that the GENEEC and PRZM/EXAMS modeling of an edge of field farm pond is not appropriate for generating accurate estimates of pesticides or degradates in actual drinking water, and should not be used directly in computing aggregate exposures for purposes of estimating human risks.

Thus, EPA should have, at the least, used the PRZM/EXAMS model as a Tier II assessment when a risk concern was raised from the use of the Tier I model.

41 ***Crack and Crevice Treatment in Homes. Application.*** Based on label directions and typical use practices, this is an acute exposure. Because exposures do not occur consecutively, the potential risk should be assessed using acute endpoints rather than the short-term toxicity values used in the current PRA. If the short-term toxicity values are used, then the exposure should be a time-weighted average over a 7-day period, as this is comparable to the exposure period from the referenced short-term toxicity study.

42 ***Mushroom House. Application.*** The second and third sentences in the final paragraph on page 42 should be corrected to read (changes in italics): "The resulting *dermal* exposure, would be 0.061 mg/kg/day. The *dermal* MOE was *1.6* with a target MOE of 100 (*remove the end parentheses).*" The MOE listed in the third sentence of 0.08 is incorrect and is not the same as on page 50

(Table 16). Additionally, there is no hand held fogger product produced or marketed. Amvac does not produce or market any "aerosol cans" of DDVP. The exposure evaluation does not reflect the changes Amvac has proposed to the dichlorvos technical label.

42 ***Mushroom House. Application.*** Based on label directions and typical use patterns, this is an acute exposure. Additionally, even if there are multiple applications, the exposures do not occur consecutively. Each exposure therefore should be assessed using acute endpoints rather than the short-term toxicity values used in the current PRA. If the short-term toxicity values are used, then the exposure should be a time-weighted average over a 7-day period, as this is comparable to the exposure period from the referenced short-term toxicity study.

43 ***Mushroom House. Post-Application***. Based on label directions and typical use patterns, this is an acute exposure. If there are multiple exposures occurring consecutively, they should be assessed by using a time-weighted average of the exposure over a 7-day period prior to comparison to the referenced toxicity values, as this is comparable to the exposure period from the referenced short-term toxicity study.

43, 44 ***Greenhouse. Application.*** Based on label directions and typical use patterns, this is an acute exposure and should be assessed using acute endpoints rather than the short-term toxicity values used in the current PRA. If the short-term toxicity values are used, then the one-day exposure should be a time-weighted average of exposures over a 7-day period, as this is comparable to the exposure period from the referenced short-term toxicity study.

44 ***Greenhouse. Post-Application.*** Based on label directions and typical use practices, post-application exposure should be characterized as an acute exposure. If multiple exposures do occur, then the exposure should be a time-weighted average of exposures over a 7-day period, as this is comparable to the exposure period from the referenced short-term toxicity study.

44 ***Domestic Animal Premises (Food and Nonfood) and Direct Animal Sprays, Feedlots, Manure Treatment, Garbage Dumps, and Baits. Application.*** Based on label directions and typical use patterns, all of these uses are acute exposure scenarios. Additionally, if multiple treatments are made, exposures do not occur consecutively. Thus, potential risk should be assessed using acute endpoints rather than the short-term toxicity values used in the current PRA. If the short-term toxicity values are used, then the exposure should be a time-

weighted average of exposures over a 7-day period, as this is comparable to the exposure period from the referenced short-term toxicity study.

44 ***Greenhouse. Post-Application.*** The oral NOAEL is stated as 0.1 mg/kg/day from an acute human study, which is not in agreement with page 16 or the rest of the document.

44 ***Greenhouse. Post-Application.*** The MOE is stated to be 1000 for occupational reentry into greenhouses by inhalation. This is not in agreement with page 17.

45 ***Warehouse Treatment. Post-Application.*** EPA assumed a 6-hour REI, which is not the label REI.

45 ***Warehouse Treatment. Application.*** Based on label directions and typical use practices, this is an acute exposure. Additionally, exposures do not occur consecutively. Thus, the potential risk should be assessed using acute endpoints rather than the short-term toxicity values used in the current PRA. If the short-term toxicity values are used, then the exposure should be a time-weighted average of exposures over a 7-day period, as this is comparable to the exposure period from the referenced short-term toxicity study.

45 ***Warehouse Treatment. Post-Application.*** Based on label directions and typical use practices, this is a short-term exposure. Exposures do not occur for more than three days (as stated in the PRA), however. Thus, this exposure should be assessed by doing a time-weighted average of the three days of exposure over a 7-day period, as this is comparable to the exposure period from the referenced short-term toxicity study.

46 ***Residential Handler. Pressurized Aerosol Spray Can***. Based on label directions and typical use practices, this is an acute exposure, not a short-term exposure. Because EPA does not assess acute residential exposures under FQPA, there is no need for a quantitative assessment. If a quantitative assessment nevertheless is conducted, either acute end-points should be used or the exposures should be averaged over a similar time-period to the toxicity study (*i.e.*, the end-point of concern is seen after 7 days of dosing; thus, exposures should be averaged over a 7-day period).

47 ***(a). Resin Pest Strips.*** The target MOE is listed as 100 (10x for intraspecies variation, 3X for interspecies variation, 3X FQPA safety factor (which equals 90, not 100). This conflicts with the uncertainty factor stated on page 16, which is 10X for interspecies, 3x for the use of a LOAEL, and 3X for FQPA.

47 ***Residential. Post-Application.*** As stated with respect to the residential handler, due to limited use of aerosol spray cans, post-application exposure reflects acute exposure. If a quantitative assessment nevertheless is conducted, either acute end-points should be used or a time-weighted average of exposures over a similar time-period to the toxicity study should be used (*i.e.*, the end-point of concern is seen after 7 days of dosing; thus, exposures should be averaged over a 7-day period). It is inappropriate to assume that exposures from a "Jazzercise" study conducted after the use of a total-release fogger would occur for up to 7 consecutive days after the use of a pressurized aerosol can.

48 ***Ornamental Lawns, Turf, and Plants. Post-Application.*** Exposure to residues of DDVP on lawns, turf, and plants may result in short-term exposure (as defined as one to seven days). The dislodgeable data used in the assessment was found to be at negligible levels within 8 to 48 hours after application, however. The current assessment is for 2 hours of exposure. This is an acute exposure and should be compared to an acute toxicity value. If a short-term assessment is conducted, then exposure period should be similar to the exposure period from the toxicity study (*i.e.*, the end-point of concern is seen after 7 days of dosing; thus, exposures should be averaged over a 7-day period).

49-55 ***Table 16.*** This table is full of errors on MOEs, etc. Many of these errors are errors that have been mentioned above (*see, e.g.*, footnotes 1 and 2 on page 53).

49-55 ***Table 16.*** EPA appears to have made changes that reflect the changes in the NOELs/NOAELs, but has not made many of the changes in exposure that reflect procedural changes, additional data, and label restrictions that Amvac has proposed. Most of these changes have been accepted by EPA. These changes, as indicated in previous comments, limit potential exposure to once every three or four weeks, as has been demonstrated in submittals to EPA. Thus, those exposures considered to be short-term exposures are now acute exposures and should be evaluated in those terms.

49 ***Table 16. Resin Pest Strips.*** The PRA does not change the resin pest strip exposure values based on the recommendation of the SAP or the revised calculation (*see* memoranda: from David Jaquith to Kimberly Lowe dated August 16, 1999, and September 1, 1999).

50 ***Table 16. Occupational Exposure Mushroom House.*** The PRA does not delete any of the application methods no longer supported by Amvac.

51 ***Table 16. Occupational Exposure Greenhouse.*** The PRA uses a 10-hour REI rather than the 24-hour REI stated on the label.

52 ***Table 16. Domestic Food/Nonfood Animals.*** The PRA does not delete any of the application methods no longer supported by Amvac.

52 ***Table 16. Domestic Animal Premises.*** The PRA does not delete any of the application methods no longer supported by Amvac.

52 ***Table 16. Warehouse Treatment.*** The exposures and MOEs presented are based on a 6-hour REI rather than the appropriate 24-hour REI based on the label.

53 ***Table 16. Footnote 2.*** The respiratory volume used is incorrect.

54 ***Table 16. Footnote 9.*** The respiratory volume used is incorrect.

54 ***Table 16. Footnote 10***. The current respiratory volume is incorrect.

54 ***Table 16. Footnote 11***. The application rate is stated to be 3 g per 1000 ft^3; the label application rate is 2 g per 1000 ft^3.

55 ***Table 16. Footnote 20.*** The REI is incorrectly stated to be 6 hours rather than the label REI of 24 hours.

Memorandum: Subject: Dichlorvos. Refined Anticipated Residues and Acute Dietary Exposure and Risk for Residues of Dichlorvos resulting from use of Dichlorvos and Naled. From Susan Hummel to Kimberly Lowe, dated April 7, 2000. Virtually all of the PDP and FDA data used in the dietary assessment are derived from crops/commodities for which there are no registered DDVP uses and on which the currently supported label does not allow use. Examples of residues from materials for which the use is not supported include a variety of fresh fruits and vegetables, especially

strawberries. The study data also are not used in a fashion that reflects the actual storage conditions practiced by industry. Amvac has submitted reports that more properly reflect industry practices (*see, e.g.,* Dietary Cancer and Non-Cancer Risk Assessment for Supported Uses, C.A. Smith, *et al.* (Dec. 20,1995)). The PRA uses a metabolism study to estimate meat, milk, poultry and egg residues when a feeding study for both cattle and chickens exists. It uses pasteurization as the "cooking factor" for milk, even though most cooked uses would result in significantly greater reductions; factors for tomato juice or coffee brewing are more appropriate for the cooking of milk.

Memorandum: Subject: Revision of Exposure Assessment for Dichlorvos (DDVP) applied to Greenhouses and Mushroom Houses. From David Jaquith to Jess Rowland, dated January 27, 1999. There are a variety of errors in this document, including: the use rates reflect application rates in excess of what is being supported; the reentry time is 24 hours (except when monitoring is done); and, Amvac has provided dislodgeable foliar residue data negating the need for the assumptions and other approaches used in this exposure assessment. The historical data (Maddy *et al.*, 1981) is neither as accurate nor as reliable as are the recent studies that have been submitted. The entire assessment needs reexamination for these reasons.

Memorandum: Subject: Error in Resin Strip Exposure Assessment for Dichlorvos (DDVP). From David Jaquith to Kimberly Lowe, dated August 16, 1999. Amvac believes that collectively, the MOEs are acceptable for the use of the pest strip when human data are used for assessing NOAELs. Nevertheless, Amvac is willing to restrict further the use of these beneficial products while the issue of the utilization of human data for defining NOAELs is debated and resolved.

Memorandum: Subject: Dislodgeable Foliar Residues and Exposure Assessment for Residential/Recreational Turf Applications of Dichlorvos (DDVP). From David Jaquith to Kimberly Lowe, dated August 13, 1999. Amvac is a member of both the ARTF and ORETF and is providing data via these Task Forces. EPA has used unusual and un-validated methods to attempt to address the exposure assessment for these use scenarios. Amvac believes that the Task Forces will submit appropriate data and methods for conducting this assessment during summer 2000. As the potential concern is limited to one DFR study, Amvac believes it is appropriate for EPA to await resolution of these issues via the Task Forces data and methodologies.

Memorandum: Subject: Response to Comments from the EXPOSAC and others on Assessment of Reentry Exposures to DDVP Resulting from Application to Residential Turf. From David Jaquith to Jess Rowland, dated January 28, 1999. This memorandum does not reflect a submittal concerning dermal transfers from pest strip use that Amvac submitted to EPA.

Memorandum: Subject: Revised Exposures to DDVP Resulting from the Use of Bait Products. From David Jaquith to Jess Rowland, dated January 27, 1999. Amvac believes that collectively, the MOEs are acceptable for this type of product when human data are used for assessing NOAELs. Nevertheless, Amvac is willing, and Amvac has stated to EPA, that it intends to revise the end-use labels for this type of product to reflect the use of gloves while the use of human data for defining NOAELs is debated and resolved.

EPA has not corrected the gross errors in its calculations based on the Blair *et al.* Study, as discussed in Amvac's February 11, 1999, comments on the prior version of the PRA.

The Revised PRA also fails to correct the fundamental misrepresentation of critical data from the Blair *et al.* Study as discussed in Amvac's February 11, 1999, comments on the prior version of the PRA.